No. 17-1594

IN THE

Supreme Court of the United States

RETURN MAIL, INC.,

Petitioner,

v.

UNITED STATES POSTAL SERVICE, ET AL.,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR *AMICUS CURIAE* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA IN SUPPORT OF PETITIONER

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INTEREST OF *AMICUS CURIAE*[1]

The Pharmaceutical Research and Manufacturers of America (PhRMA) is a voluntary, nonprofit association representing the Nation's leading research-based biopharmaceutical companies. PhRMA's members research and develop innovative medicines, treatments, and vaccines that save, prolong, and improve the quality of lives of countless individuals around the world every day.

The question presented in this case is whether the federal government may participate—on unequal terms—in the post-grant patent review proceedings created by the Leahy-Smith America Invents Act (AIA). PhRMA has a profound interest in the sound resolution of this question. Since 2000, PhRMA member companies have invested more than $600 billion in the search for new treatments and cures, including an estimated $71.4 billion in 2017 alone. PhRMA member companies rely on a fair and predictable patent system to protect the innovations resulting from those enormous investments. PhRMA's members are frequent participants in AIA administrative proceedings. PhRMA thus has unique insights on the implications of the issue before the Court, as well as the need for an equitable patent system that fosters, rewards, and protects innovation and competition alike.

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[1] The parties have consented to the filing of this brief. Copies of letters granting consent have been filed with the Clerk. No counsel for a party authored this brief in whole or in part, and no person, other than *amicus*, its members, or their counsel, made any monetary contribution to the preparation or submission of this brief.

SUMMARY OF ARGUMENT

The decision below creates an untenable situation in American patent law. The Federal Circuit held that the U.S. Postal Service, an agency of the federal government, is a "person" capable of initiating administrative proceedings under the AIA to challenge the validity of a Covered Business Method (CBM) patent. The logic of the Federal Circuit's decision applies not just to CBM reviews, but to the two other types of review proceedings under the AIA: *inter partes* reviews and post-grant reviews. Under the Federal Circuit's view of the law, however, the government, unlike private petitioners in AIA review proceedings, would be free to mount a subsequent challenge to the same patent on the same grounds in court regardless of the outcome of the AIA administrative adjudication. Thus, like a beneficiary of the proverbial coin toss in which "heads I win, tails you lose," the government, according to the Federal Circuit, can win an AIA administrative proceeding, but it can never really lose one. This result is directly at odds with the AIA's intended purpose of creating an efficient alternative to litigation. It is not and cannot be what Congress intended. This Court should reverse the decision below.

The Federal Circuit's reading of the AIA would undercut one of the AIA's core goals: providing a set of administrative procedures that would make the resolution of challenges to the validity of patents more efficient and less expensive—for patentees and challengers alike—than the alternative of infringement litigation. *See* H.R. Rep. No. 112-98, pt. 1, at 48 (2011) (AIA review a "quick and cost-effective alternativ[e] to litigation"); *see also* S. Rep. No. 110-259, at 20 (2008); *Cuozzo Speed Techs., LLC* v. *Lee*, 136 S. Ct. 2131, 2143 (2016). By enabling parties to secure swift and *final* resolu-

tions of patent validity disputes before the Patent Trial and Appeal Board (PTAB), an adjudicative body within the U.S. Patent and Trademark Office (USPTO), the AIA responded to longstanding and growing concerns about the rising costs of patent litigation. Congress ensured the finality of these PTAB determinations by including a corresponding estoppel provision: unsuccessful AIA petitioners may not challenge the validity of the patent at issue on the same grounds in district courts or in the International Trade Commission (ITC).

But if the government is a "person" for purposes of these administrative review mechanisms, as the Federal Circuit held, the proceedings the AIA creates would have no finality. Patent owners may seek redress for infringement by the government only through actions under 28 U.S.C. § 1498 in the Court of Federal Claims, a forum to which the AIA's estoppel provision does not apply. Such a result is contrary to the statute's design and would entirely defeat Congress's purpose. The absence of an estoppel provision for Section 1498 actions only demonstrates that Congress did not intend for the government to qualify as a "person" for purposes of the AIA's administrative review proceedings.

The Federal Circuit's decision is also troubling because it would permit the use of administrative adjudication to resolve what are effectively inter-agency legal disputes. Allowing one arm of the Executive Branch to challenge a prior determination by another arm in this way is highly unusual. And our government has criticized foreign intellectual property regimes for permitting arrangements analogous to the one that the Federal Circuit's ruling would authorize.

This Court should reverse the Federal Circuit's judgment and hold that federal agencies do not qualify

as "person[s]" capable of instituting administrative review proceedings under the AIA.

ARGUMENT

The AIA creates three mechanisms that "allow[] private parties to challenge previously issued patent claims in an adversarial process before the Patent Office that mimics civil litigation." *SAS Inst., Inc.* v. *Iancu*, 138 S. Ct. 1348, 1352 (2018). Subject to various limitations, these mechanisms—*inter partes* review, post-grant review, and CBM review—are available to any "person who is not the owner of a patent" subject to review. 35 U.S.C. §§ 311(a), 321(a); AIA § 18(a)(1)(B), Pub. L. No. 112-29, 125 Stat. 284, 330 (2011). In exchange, that "person" is estopped from contesting the validity of the challenged patent claims in actions for patent infringement in district courts or before the ITC "on any ground that the petitioner raised or reasonably could have raised" during AIA administrative review. 35 U.S.C. §§ 315(e)(2), 325(e)(2); *accord* AIA § 18(a)(1)(D), 125 Stat. at 330 (similar).

Because sovereign immunity shields the government from patent infringement suits in district court, *see Schillinger* v. *United States*, 155 U.S. 163, 167-169 (1894), patent owners whose intellectual property has been appropriated by the government must seek redress in the Court of Federal Claims under 28 U.S.C. § 1498(a), *see Crozier* v. *Fried. Krupp Aktiengesellschaft*, 224 U.S. 488, 305, 309 (1912). The AIA's estoppel provisions, however, do not apply to Section 1498(a) actions. The reason for this omission is simple: the government is not a "person" within the meaning of the AIA's administrative review procedures.

I. ESTOPPEL IS AN INDISPENSABLE COMPONENT OF THE AIA'S STRUCTURE

AIA administrative review proceedings are designed to provide expeditious and final resolution of challenges to the validity of patent claims and thus to serve as an alternative to the more time-consuming and expensive path of litigation. The Federal Circuit's decision would undermine this fundamental purpose of the reforms put in place by the AIA. By leaving the government unencumbered by the AIA's estoppel provisions, the Federal Circuit's ruling would enable the government to ignore adverse PTAB determinations and use AIA reviews to impose an extra round of adjudication and greater costs on patent owners, courts, and the PTAB. Giving the government this estoppel exception is inconsistent not only with one of the AIA's core goals but also with this Court's articulation of the functions of estoppel doctrine.

A. AIA Administrative Reviews Were Intended To Serve The Twin Goals Of Efficiency And Finality

Congress sought to achieve two things in establishing the AIA's administrative review processes. First, it intended to create a "quick and cost-effective alternativ[e] to litigation." H.R. Rep. No. 112-98, pt. 1, at 48 (2011) ("House Report"); *see also* S. Rep. No. 110-259, at 20 (2008) (post-grant review "a quick, inexpensive, and reliable alternative to district court litigation"); *Cuozzo Speed Techs., LLC* v. *Lee*, 136 S. Ct. 2131, 2143 (2016). The AIA seeks to achieve this goal by requiring, for example, that an *inter partes* review petition be brought within a year of the patent owner's allegation of infringement, 35 U.S.C. § 315(b), and by setting a 12- to 18-month deadline for the PTAB to rule on petitions,

id. §§ 316(a)(11), 326(a)(11); AIA § 18(a)(1), 125 Stat. at 329; *see also* House Report at 47 (describing intent of these provisions).[2] Congress also created PTAB procedures that would "force parties to frontload their cases, allowing these proceedings be resolved more quickly." 157 Cong. Rec. 2830, 2849 (2011) (statement of Sen. Kyl); *see* 35 U.S.C. §§ 312(a)(3), 322(a)(3) (requiring petitions for review to identify "each claim challenged, the grounds on which the challenge to each claim is based, and the evidence that supports the grounds for the challenge to each claim" "with particularity"). Expeditiousness provides both patent challengers and patentees with a prompt determination of their rights.

Second, Congress intended to ensure the finality of PTAB rulings. It did so by giving them preclusive effect in district courts and the ITC, which would "protect the rights of inventors and patent owners against new patent challenges unbounded in time and scope." House Report at 47-48 (2011). Thus, AIA proceedings would serve as the functional equivalent of actions for "quiet title to patent owners." *Id.* at 48. "[P]atentees who successfully go through the post-grant system" were to reap "significant advantages" because their "patent is largely unchallengeable by the same party." *America Invents Act: Hearing on H.R. 1249 Before the Subcomm. on Intellectual Property, Competition, and the Internet of the H. Comm. on the Judiciary*, 112th Cong. 52-53 (2011) ("*House Hearing*") (statement of USPTO Director David Kappos). As Judge Newman explained in her dissent below, "[t]he estoppel provision is the backbone of the AIA, for it is through estop-

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[2] The Director of the USPTO is also required to act on a petition within three months of receiving the patent owner's preliminary response. 35 U.S.C. §§ 314(b), 324(b); AIA § 18(a)(1), 125 Stat. at 329.

pel that the AIA achieves its purpose of expeditious and economical resolution of patent disputes[.]" Pet. App. 51a.

During consideration of an earlier version of the bill that became the AIA, then-USPTO Director Jon Dudas explained that the goals of efficiency and finality were interdependent, telling the Senate Judiciary Committee that "the estoppel needs to be quite strong" to ensure that AIA proceedings would be "a complete alternative to litigation." *Patent Reform: The Future of American Innovation: Hearing Before the Senate Comm. on the Judiciary*, 110th Cong. 13 (2007) (statement of USPTO Director Jon Dudas). The AIA's administrative adjudication pathways, Dudas's successor similarly told Congress, would "minimize costs and increase certainty" in patent-dependent fields. *House Hearing* at 45 (2011) (statement of USPTO Director David Kappos). The reduced costs and increased clarity about patent rights that the AIA's administrative review procedures would bring, Congress believed, would encourage innovators to enter the market and ensure continued investment in new technologies. *See* House Report at 48.

B. Government Initiation Of AIA Proceedings Without Estoppel Undermines Both Of These Goals

Permitting federal agencies to bring petitions for review in AIA proceedings would subvert the AIA's twin goals of promoting efficiency and finality in the resolution of patent validity disputes.

If the government appropriates a patent holder's intellectual property, the patent holder can file a 28 U.S.C. § 1498(a) action in the Court of Federal Claims.

If the Federal Circuit's ruling is permitted to stand, the government could then seek AIA review of the patent. If the government wins and invalidates a claim in a patent, the patent holder's Section 1498(a) action would fail with respect to that claim because that claim would be cancelled, and the patent owner would no longer have a cause of action with respect to it. *See* 28 U.S.C. § 1498(a) (requiring that the infringed invention be "covered by a patent"). But if the government loses before the PTAB, it could return to the Court of Federal Claims and raise the same invalidity arguments it used in the AIA proceeding as a defense against the Section 1498(a) claim.

This scenario worsens the very problems Congress set out to address in creating the AIA's administrative review proceedings. First, the PTAB's involvement would extend the litigation if the Court of Federal Claims stays the litigation pending the outcome of the AIA proceeding. The patent owner may have to endure not one but two challenges to its intellectual property rights—based on identical arguments. Such an outcome conflicts with Congress's intent to prevent "serial challenges to patents" and "endless litigation." 157 Cong. Rec. 2687, 2710 (2011) (statement of Sen. Grassley). Whereas Congress sought to minimize costs and increase certainty, this scenario would increase costs and foster uncertainty.

Second, the PTAB's ruling would not be final. The patent owner would be deprived of the "significant advantage[]" of quiet title to its patent. *House Hearing* at 52 (statement of USPTO Director David Kappos). Exacerbating this harm is the fact that the government would still reap the benefits of the AIA review: if the government secures a PTAB determination of invalidity, it will prevail in the Section 1498(a) action because

the cancellation of the relevant claim undercuts the cause of action with respect to that claim.

This scenario shows how the Federal Circuit's reading of the AIA would frustrate rather than advance Congress's aim to create a set of expeditious procedures to resolve patent disputes with finality. Congress could not have intended to undercut a fundamental purpose of the AIA in this way merely by omitting Section 1498(a) from the estoppel provisions applicable to the AIA's administrative review processes. As this Court has explained, "Congress ... does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions." *Whitman* v. *American Trucking Ass'ns*, 531 U.S. 457, 468 (2001).

C. No Sound Reason Exists Why Congress Would Have Given The Government An Estoppel Exemption

As this Court has long recognized, estoppel is necessary to ensure "the conclusive resolution of disputes." *Montana* v. *United States*, 440 U.S. 147, 153 (1979) (citing *Southern Pac. R. Co.* v. *United States*, 168 U.S. 1, 49 (1897)). To that end the Court has "broadened the scope of the doctrine of collateral estoppel beyond its common law limits." *United States* v. *Mendoza*, 464 U.S. 154, 158-159 (1984). In general, collateral estoppel applies to the government. *See United States* v. *Stauffer Chem. Co.*, 464 U.S. 165, 169 (1984) ("[T]he doctrine of mutual defensive collateral estoppel is applicable against the Government[.]"); *Montana*, 440 U.S. at 164 (estopping the government from "seeking a contrary resolution of those issues" that "it had a full and fair opportunity to press" in a prior case).

The government is only typically exempt from one species of estoppel: "nonmutual offensive collateral estoppel," which prevents re-litigation of a resolved issue against non-parties to the original litigation. *Mendoza*, 464 U.S. at 162. In explaining the basis for that exemption, this Court reasoned that the government is often party to multiple cases involving similar, important constitutional and public rights issues. Estoppel against the government in such cases "would substantially thwart the development of important questions of law by freezing the first final decision rendered on a particular legal issue." *Id.* at 160.

None of these concerns are present in AIA review proceedings or Section 1498(a) actions. Although this Court has held that the decision to grant a patent and the AIA *inter partes* process fall within the public rights doctrine, *see Oil States Energy Servs., LLC* v. *Greene's Energy Grp., LLC*, 138 S. Ct. 1365, 1373, 1375 (2018), the validity of particular claims in particular patents is a far cry from the kind of recurring "legal questions of substantial public importance" that this Court considered central to the justification for the government exemption from one form of estoppel doctrine, *Mendoza*, 464 U.S. at 160.

And the standing requirements for bringing patent infringement claims in district court all but guarantee the mutuality of parties. AIA reviews involve the petitioner and the patent owner. *E.g.*, 35 U.S.C. §§ 313, 323; AIA § 18(a)(1), 125 Stat. at 329. The Federal Circuit has held that only "'patentee[s]'"—that is, "'the entity to whom the patent was issued'" and its "'successors in title'"—and exclusive licensees suing "jointly with the patent owner" have standing to bring infringement claims in district court. *Intellectual Prop. Dev., Inc.* v. *TCI Cablevision of Calif., Inc.*, 248 F.3d

1333, 1346-1348 (Fed. Cir. 2001) (quoting 35 U.S.C. § 100(d)); *see also* 35 U.S.C. § 281 (limiting "remedy by civil action for infringement" to the "patentee").[3]

The Federal Circuit's interpretation of the AIA would create an estoppel exemption for the government that cannot be justified based on the purposes of the doctrine, as this Court has set out those purposes.

D. The Estoppel Exemption Created By The Federal Circuit Would Exacerbate Existing Imbalances In AIA Reviews

In *Oil States*, this Court reserved judgment on whether AIA review proceedings comply with due process. 138 S. Ct. at 1379. And experience so far suggests that AIA review proceedings already afford a favorable forum for patent challengers. In fiscal year 2018, for example, the PTAB instituted review on 60% of all AIA petitions. USPTO, Patent Trial and Appeal Board Statistics, slide 6 (2018), https://bit.ly/2QYk4FE. Since the AIA was enacted, the PTAB has invalidated claims in 80% of cases in which it has instituted proceedings. *Id.* at slide 10. Consistent with these statistics, the Chief Judge of the PTAB in 2014 described the purpose of AIA review proceedings as "death squadding" challenged patent claims. PTAB Chief Judge James Donald Smith, Transcript of Patent Public Advisory Committee quarterly meeting, morning session 128-130 (Aug. 14, 2014), https://bit.ly/2EpaZir. By contrast, a 2014 study showed that patent challengers prevail on invalidity claims in

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[3] Another estoppel exception exists for "'unmixed questions of law' arising in 'successive actions involving unrelated subject matter.'" *Stauffer*, 464 U.S. at 171 (quoting *Montana*, 440 U.S. at 162); *see also United States* v. *Moser*, 266 U.S. 236, 242 (1924). For similar reasons, this exception is also inapposite here.

district courts only 42% of the time. *See* Allison et al., *Understanding the Realities of Modern Patent Litigation*, 92 Tex. L. Rev. 1769, 1794 (2014).

Even as it is, AIA review has not achieved the balance Congress sought to strike between efficiency and finality. In one illustrative case, one of our member companies was subjected to *inter partes* review on the same arguments after its patent claims were upheld on the same grounds by two district courts and the Federal Circuit. The innovator first successfully enforced its patents against a generic drug maker, proving infringement. *Novartis Pharm. Corp.* v. *Par Pharm., Inc*, 48 F. Supp. 3d 733 (D. Del. 2014), *aff'd*, 611 F. App'x 988 (Fed. Cir. 2015). The court also held that the generic failed to show that the claims of two of the innovator's patents were invalid, and the Federal Circuit affirmed. *Novartis Pharm. Corp.* v. *Watson Labs., Inc.*, 611 F. App'x 988 (Fed. Cir. 2015). Then the innovator successfully enforced its patents against a second generic company and won. *Novartis Pharm. Corp.* v. *Noven Pharm., Inc.*, 135 F. Supp. 3d 474 (D. Del. 2015). Meanwhile the second generic petitioned for *inter partes* review and secured a determination of unpatentability from the PTAB that the Federal Circuit affirmed, notwithstanding its prior ruling upholding the claims in the first litigation. *Novartis AG* v. *Noven Pharm., Inc.*, 853 F.3d 1289 (Fed. Cir. 2017). This case demonstrates the uncertainty that AIA review introduces for patent owners, including in the pharmaceutical industry.

Although the USPTO has recently taken some steps to provide more certainty in post-grant proceedings, such as changing the claim construction standard to the one used in district courts, imbalances under the AIA remain.

As noted above, questions about the constitutionality of AIA review procedures also remain outstanding. *Oil States*, 138 S. Ct. at 1379. Providing the government an estoppel exemption, as the Federal Circuit did, would only further unsettle patent owners' reasonable expectations.

II. Permitting One Federal Agency To Challenge Determinations By Another Agency In An Administrative Forum Would Be Anomalous

A second fundamental reason the Federal Circuit's interpretation of the AIA should be rejected is that it would allow an inter-agency dispute resolution mechanism of a kind Congress has rarely authorized. The United States has explicitly criticized similar systems in the intellectual property regimes of foreign countries.

A. One Agency's Participation In The Adjudicative Processes Of Another Is Disfavored

"The Constitution vests the 'executive Power' in one President" and "assigns the President the responsibility to 'take Care that the Laws be faithfully executed.'" *SEC* v. *Federal Labor Relations Auth.*, 568 F.3d 990, 997 (D.C. Cir. 2009) (Kavanaugh, J., concurring) (quoting U.S. Const. art. II). The "[e]xecutive power ... includes the authority to supervise and resolve disputes between [the President's] subordinates." Mem. of Disapproval for the Whistleblower Protection Act of 1988, 24 Weekly Comp. Pres. Doc. 1377, 1378 (Oct. 26, 1988). Thus because "a single President controls the Executive Branch, legal ... disputes between two Executive Branch agencies are typically resolved by the President." *Federal Labor Relations Auth.*, 568 F.3d at 997 (Kavanaugh, J., concurring). Routing inter-agency legal disputes through administrative adjudica-

tion makes an end run around this more typical and well-established method for resolving legal disputes within the Executive Branch.

Consistent with these principles, "[b]y placing a decision in the hands of a particular agency, Congress has implied that it does not want other agencies to gum up the works." Herz, United States v. United States: *When Can the Federal Government Sue Itself?*, 32 Wm. & Mary L. Rev. 893, 973 (1991). Here, Congress has placed patent validity decisions in the hands of the USPTO. "We can infer from Congress' decision to place the final determination with the [agency] that it does not want other persons or agencies, to which it chose not to give this authority, to interfere with the [agency's] execution of that responsibility." *Id.*

Consistent with this understanding, the Administrative Procedure Act (APA), which sets forth the default rules for agency adjudications, does not provide for the inclusion of other agencies in adjudications. For instance, 5 U.S.C. § 554(b) sets forth notice requirements for formal agency adjudications. The entities entitled to notice are limited to "persons." The APA's definition of "person" "includes an individual, partnership, cooperation, association, or public or private organization *other than an agency*." 5 U.S.C. § 551(2) (emphasis added).

Although Congress has in rare instances authorized one agency to initiate or intervene in administrative adjudications by another agency, *see Secretary of Agric. of U.S.* v. *United States*, 347 U.S. 645, 647 (1954) (challenge to railroad rates set by the Interstate Commerce Commission); *Udall* v. *Federal Power Comm'n*, 387 U.S. 428, 433 (1967) (Department of the Interior intervened in a Federal Power Commission adjudication regarding a municipality's application to operate a

hydroelectric power facility), such participation has typically involved important issues of public policy rather than protection of property rights held by the government itself.[4] Without any express authorization in the text of the AIA, the Federal Circuit's interpretation runs contrary to the predominant approach of excluding federal agencies from participating in the adjudications of other agencies and undermines Congress's intent to entrust the USPTO with lead responsibility for administrative patentability determinations. For these reasons too its interpretation of the AIA should be rejected.

B. The United States Has Criticized Similar Systems In Other Countries

The United States has expressed "longstanding concern" regarding situations in which foreign governments empower agencies other than their national patent offices to question the validity of patents or otherwise participate in the patent-granting process. *See* Office of the U.S. Trade Representative, 2017 Special 301 Report, at 66, https://bit.ly/2oFseWb (visited Dec. 17, 2018). For instance, Brazilian law allows that country's Health Regulatory Agency to participate in the review process for pharmaceutical patents. This agency, which lacks technical expertise on patentability requirements, often applies criteria contradictory or additive to those employed by the Brazilian patent authority. The uncertainty and delays this duplicative review process creates have been a matter of contention between the U.S. and Brazilian governments for

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[4] In *United States* v. *ICC*, 337 U.S. 426 (1949), the U.S. Army challenged before the ICC rates charged the Army by several railroads.

several years. *See id.* at 66-67; *see also id.* at 67 (criticizing proposal for a similar system in Colombia).

The United States voiced these concerns well before Congress passed the AIA. *See, e.g.*, Office of the U.S. Trade Representative, 2009 Special 301 Report, at 23, https://bit.ly/2rHujQd (visited Dec. 17, 2018). It is exceedingly unlikely that Congress intended in the AIA to replicate patent review systems that the Executive Branch has criticized. *Cf. McCulloch* v. *Sociedad Nacional de Marineros de Honduras*, 372 U.S. 10, 20-21 (1963) (declining to construe a statute in a manner that would run "contrary to" the policy of "our State Department"). While the USPTO may have authority to revisit its own decisions in AIA proceedings, other agencies of the government without expertise (or even competence) in patent matters should not be given a privileged place in questioning the presumed validity of a duly-issued patent. Allowing one agency of the government to effectively challenge the decision of the agency with special expertise in patent matters would magnify the uncertainty about patent rights that the AIA was intended to reduce and would undermine confidence in the patent-granting system that companies such as *amicus*'s members need to continue to invest in innovation.

CONCLUSION

The Court should reverse the judgment below.

Respectfully submitted.

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DECEMBER 2018